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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/700,040

11/02/2003

Birinder R. Boveja

3426

43987

7590

06/12/2006

BIRINDER R. BOVEJA & ANGELY WIDHANY

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EXAMINER

LEE, YUN HAENG NMN

ART UNIT

PAPER NUMBER

3766

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/700,040	BOVEJA, BIRINDER R.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yun H. Lee	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 23-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/2/2003</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group II, Claims 1-22 in the reply filed on 5/30/2006 is acknowledged. The traversal is on the ground(s) that the apparatus as claimed cannot be used to practice another and materially different process such as cardiac stimulation. This is not found persuasive because the apparatus as claimed merely claims a stimulation means and a programming means. This type of apparatus can clearly be used to stimulate any part of the human body including the heart, the brain, the spinal cord, etc. The traversal is further on the ground that searching and examining all of the claims would not impose a serious burden on Examiner, particularly since all the pending claims have been categorized in the same class and subclass. Although the same classification is indicated, the classification contains numerous different inventions and embodiments that have acquired a separate status in the art. Further, the broad "catch-all" subclass 607/2 in the US classification system may not be adequately broken out to account for different types of systems and methods. By way of example, prior to reclassification efforts, pacemakers and defibrillators for years were classified under the same subclass even though these inventions clearly would be considered distinct by those skilled in the cardiac treatment arts.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 101***

2. Claims 2 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. It has been held that computer data structures and programs per se are not statutory subject matter (MPEP 2106 IV B 1(a)). Examiner suggests amending the limitation to specify a tangible physical medium which contains the computer program.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-12 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. (US Pat. No. 5,707,400).

Regarding claim 1, Terry Jr. et al. clearly discloses the method of claim 1 except for the means for networking with remote computers for data exchange. Examiner takes Official Notice that it is old and well known in the art to include means for networking with remote computers for data exchange in a programmer for an implantable medical device. This type of means provides the advantage of enabling an expert physician to monitor and deliver therapy to a patient from a remote location without having to be physically present. It also provides the advantage of providing the implantable medical

Art Unit: 3766

device with access to a plethora of information available in various databases which can be used by the device when making decisions. Thus, it would have been obvious for one of ordinary skill in the art at the time of invention to include a means for networking with remote computers for data exchange in the programmer means of Terry, Jr. et al.

Regarding claim 2, Terry Jr. et al. discloses the stimulation means comprising an implantable pulse generator (13) capable of executing a program (col. 6 line 35) which is activated with a magnet (col. 6 lines 20-21). Although Terry Jr. et al. does not disclose expressly the presence of two or more fixed programs, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include at least two fixed programs within the invention of Terry Jr. et al. since Applicant has not disclosed that having at least two fixed programs provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the invention of Terry Jr. et al. Therefore, it would have been an obvious matter of design choice to modify the invention of Terry Jr. et al. to obtain the invention as specified in claim 2.

Regarding claim 3, Terry Jr. et al. discloses an external magnet (col. 6 line 21).

Examiner takes Official Notice that it is old and well known in the art to use an RF or electromagnetic link that couples power from an external coil to an internal coil in order

Art Unit: 3766

to power an implanted device and/or to charge a battery or other charge storage device such as a capacitor, and also to transfer data between an external device such as a programmer and the implanted device. It is well known to power an implanted medical device with a battery that is housed internal to the implanted device. However, any battery used for extended periods of time will eventually need to be either recharged or replaced. Replacing an internally implanted battery subjects the patient to further surgery and thus is not desirable. Although it is known to power an implanted medical device through a lead connected to the device and extending outside the patient's body, any lead that passes through the skin increases the risk of infection and thus is not desirable. An RF or electromagnetic link that couples power from an external coil to an internal coil can be used to solve these problems and thus it would have been obvious to one of ordinary skill in the art at the time of invention to include in the invention of Terry Jr. et al. an RF or electromagnetic link that couples power from an external coil to an internal coil to power an implanted device and/or to charge a battery or other charge storage device such as a capacitor, and also to transfer data between an external device such as a programmer and the implanted device.

Regarding claim 4, an external coil is an external stimulator.

Regarding claim 5, an external coil is also a telemetry means for networking with the internal coil.

Regarding claim 6, Terry Jr. et al. discloses a telemetry unit (35, 36) for networking.

Regarding claim 7, see the above discussion of claim 1.

Regarding claim 8, in view of the above discussion of an RF or electromagnetic link, an internal coil is an implanted stimulus-receiver and an external coil is an external stimulator for delivering power and data. The internal coil will inherently comprise circuitry which is needed to transfer power to the implanted device. Terry Jr. et al. does not expressly disclose a high-value capacitor for storing charge. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to include a high-value capacitor for storing charge in the implanted stimulus-receiver discussed above since Applicant has not disclosed that the high-value capacitor provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the modified invention of Terry Jr. et al. as discussed above. Therefore, it would have been an obvious matter of design choice to further modify the modified invention of Terry Jr. et al. discussed above to obtain the invention as specified in claim 8.

Regarding claim 9, the limitations are met by the above discussions of claim 2 and 8.

Art Unit: 3766

Regarding claims 10-12, all the limitations are met by the above discussions except for providing a lead in connection with said implantable pulse generator means, and adapted to be in contact with the said vagus nerve, which is disclosed in Terry Jr. et al. col. 5 lines 35-40.

Regarding claims 18-22, all the limitations are met by the above discussions except for the vagal stimulation leading to an increased cardiac parasympathetic tone which is inherent in vagal stimulation.

5. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry, Jr. et al. (US Pat. No. 5,707,400) in view of Terry, Jr. et al. (US Pat. No. 6,622,041). All the limitations are met by the above discussions except for the therapy being for congestive heart failure. Terry, Jr. et al. '041 teaches of stimulating the vagus nerve to treat patients suffering from congestive heart failure. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to use the invention of Terry, Jr. et al. '400 to treat congestive heart failure.

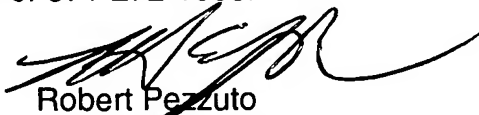
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Robert Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766

yhl